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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,768	02/27/2002	William J. Dower	PK3065US3	3351
23347	7590	02/25/2005		
DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY GLAXOSMITHKLINE FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER	
			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/083,768	DOWER ET AL.
Examiner	Art Unit	
Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11-18-04.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-4 and 11-27 is/are pending in the application.  
4a) Of the above claim(s) 2,4,11-14 and 21 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,3,15-20 and 27 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-27-02.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of the species EGPTLRQWL in the reply filed on 11-18-04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted on the elected species EGPTLRQWL and was determined to be free of the prior art. The search was extended to the species of claims 15 and 16 and were determined to be free of the prior art. The search was finally extended to the broad Markush and where prior art, Foxwell et al, was found and applied against the claims. Thus, in accordance with election of species practice, claims 1, 3, 15-20, 27 have been examined as drawn to elected species. Claims 2, 4, 11-14, 21-26 have been withdrawn from consideration as drawn to non-elected species. Note that claims 21-26 are drawn to the peptide conjugated to a non-proteinaceous polymer. This complex is patentably distinct from a peptide conjugated to a detectable label such as radioisotopes, enzymes, fluorescent labels. Thus, these claims correspond to non-elected species.

### *Claim Objections*

2. Claims 1, 3, 15-18 are objected to because of the following informalities:

In claim 16, the lines corresponding to the bonds are imnproperly aligned. For example, for SEQ ID. 17 and 18, the bond line should be between the Alanine residue for SEQ ID. 17 and Lysine. The picture disclosed does not depict this.

In claim 1, for variable X4, applicants are requested to replace "coded" with "encoded."

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "said peptide" in base claim 16. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Foxwell et al. (GB 2186579).

The claims are drawn to a peptide having a molecular weight of less than 8000 and comprising the a sequence of the amino acid (SEQ ID. 2) having a detectable label covalently attached to said peptide.

The reference disclose the peptide Leu-Arg-Arg-Ala-Ser-Leu-Gly (kemptide) that corresponds to the formula of SEQ ID. 2 (see page 1, lines 100-102). The reference discloses that

this peptide is labeled with P32, thereby meeting the limitation of the detectable label of claim 1.

The disclosed peptide is OX7-Kemptide-<sup>32</sup>P (see page 5, example 11).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20, 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-31 of U.S. Patent No. 6,083,913 and Dower (US 6465430)

It is noted that claims 2, 4, 11-14 have been included in this rejection. This has been done for the purposes of expediting prosecution and should not be construed as if the search was extended to the withdrawn claims.

The claims are drawn to a peptide having a molecular weight of less than 8000 and comprising the a sequence of the amino acid (SEQ ID. 2) having a detectable label covalently attached to said peptide.

The US Patent claims peptides that have a molecular weight of less than 8000 daltons and have a sequence corresponding to the formula X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>X<sub>5</sub>X<sub>6</sub>X<sub>7</sub> (see claim 6). This formula is the same formula with the same variable definitions for each X as claimed in claim 1 of the instant

application. Claim 19 of the US Patent claims the same peptides as claimed in claim 15 of the US patent. Specifically, the US patent claims the peptide IEGPTLRQWLAARA, in claim 19 which corresponds to the sequence of claim 27 of the instant application. The US patent claims that the peptides bind to the thrombopoietin receptor and specifically claims the peptide of SEQ ID 17 and 18 as one of those preferred peptides (see claim 30). The difference between the US Patent claims and the instant application claims is that the US Patent does not disclose the use of a label.

However, US patent 6506362 discloses the peptide of sequence ID 17 and 18 with an attached detectable label (see claim 1 and 16). Note that the sequence disclosed is the same as the sequence disclosed in claim 16 of the instant application. Thus, it would have been obvious to label the claimed peptides because one could monitor the binding of the peptides to the thrombopoietin receptor.

*Different Inventors, Common Assignee, Obvious Inventions, No Evidence  
of Common Ownership at Time of Invention*

6. Claim 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 16 of U.S. Patent No. US 6506362. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

US patent 6506362 claims the peptide of sequence ID 17 and 18 with an attached detectable label (see claim 1 and 16). Note that the sequence disclosed is the same as the sequence disclosed in claim 16 of the instant application (last peptide). The labels are enzymes, radioisotopes, and fluorescent labels, similar to the claimed invention (see claim 2 of the US Patent and claim 17 of the

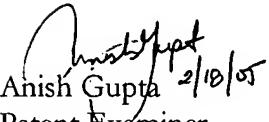
instant application). Thus, the US Patent sufficiently claims labeled compounds to anticipate the claimed invention.

Claims 16-17 are directed to an invention not patentably distinct from claims 1-2 and 16 of commonly assigned US 6506362. Specifically, US patent 6506362 claims the peptide of sequence ID 17 and 18 with an attached detectable label (see claim 1 and 16). Note that the sequence disclosed is the same as the sequence disclosed in claim 16 of the instant application (last peptide). The labels are enzymes, radioisotopes, and fluorescent labels, similar to the claimed invention (see claim 2 of the US Patent and claim 17 of the instant application). Thus, the US Patent sufficiently claims labeled compounds to anticipate the claimed invention.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6506362, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

  
Anish Gupta 2/10/05  
Patent Examiner

  
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